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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2013-0225; FRL-9915-63]

RIN 2070-AJ99

Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Toxic Substances Control Act (TSCA), EPA is proposing to amend a significant new use rule (SNUR) for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances by designating as a significant new use manufacturing (including importing) or processing of an identified subset of LCPFAC chemical substances for any use that will not be ongoing after December 31, 2015, and all other LCPFAC chemicals substances for which there are currently no ongoing uses. For this SNUR, EPA is also proposing to make inapplicable the exemption for persons who import LCPFAC chemical substances as part of articles. In addition, EPA is also proposing to amend a SNUR for perfluoroalkyl sulfonate (PFAS) chemical substances that would make inapplicable the exemption for persons who import PFAS chemical substances as part of carpets. Persons subject to these SNURs would be required to notify EPA at least 90 days before commencing such manufacture or processing. The required notifications would provide EPA with the opportunity to evaluate the intended use and, if necessary, an opportunity to protect against potential unreasonable risks from that activity before it occurs.

DATES: Comments must be received on or before [insert date 60 days after date of publication in the Federal Register].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0225, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Nicholas Nairn-Birch, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3668; email address: nairn-birch.nicholas@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including import) or process any of the chemical substances covered by this proposed SNUR. The North American Industrial Classification System (NAICS) codes that are identified in this unit are not intended to be exhaustive, but rather provides a guide to help readers determine whether this rule applies to them. Potentially affected entities may include:

- Manufacturers (including importers) of one or more of subject chemical substances (NAICS codes 325 and 324110); e.g., chemical manufacturing and petroleum refineries.
 - Fiber, yarn, and thread mills (NAICS code 31311).
 - Carpet and rug mills (NAICS code 314110).
 - Home furnishing merchant wholesalers (NAICS code 423220).
 - Carpet and upholstery cleaning services (NAICS code 561740).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or

after [insert date 30 days after the date of publication in the **Federal Register**] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 721.5 and 40 CFR 721.9582. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER**INFORMATION CONTACT.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. What Action is the Agency Taking?

EPA is proposing to amend a SNUR at 40 CFR 721.10536 for LCPFAC chemical substances by designating manufacturing (including importing) or processing of LCPFAC chemical substances listed in Table 1 of this unit for any use that is no longer ongoing after December 31, 2015, as a significant new use; designating manufacturing (including importing) or processing of PFOA or its salts for any use as a significant new

use; and designating manufacturing (including importing) or processing of all other LCPFAC chemical substances for any use not ongoing as of the date on which this proposed rule is published as a significant new use. For this SNUR, EPA is also proposing to make the exemption at 40 CFR 721.45(f) inapplicable for persons who import LCPFAC chemical substances listed in Table 1 of this unit and PFOA or its salts as part of articles because exposure would increase if in the future LCPFAC chemical substances, including PFOA, are incorporated in articles and then imported. EPA is also proposing to amend a SNUR at 40 CFR 721.9582 for PFAS chemical substances to make the exemption at 40 CFR 721.45(f) inapplicable for persons who import of PFAS chemical substances as part of carpets. This action is consistent with the purpose of the "Long-Chain Perfluorinated Chemicals Action Plan" (2009 Action Plan) published on December 30, 2009 (Ref. 1). EPA is continuing to assess these chemical substances to determine what other actions would be warranted. Before promulgating a final SNUR with respect to uses of LCPFAC chemical substances listed in Table 1 of this unit that are now ongoing, but are expected to be phased out by December 31, 2015, EPA will verify through comments on this action, or by other means, that the proposed significant new uses have indeed ceased. Similarly, before promulgating a final SNUR on LCPFAC chemical substances other than those listed in Table 1 of this unit, EPA will determine based on comments on this action and other means what if any uses are ongoing in making significant new use determinations in the final rule. Persons would be required to notify EPA at least 90 days before commencing manufacture or processing of LCPFAC chemical substances for the designated significant new uses. This proposed SNUR is intended to follow and codify an existing voluntary industry commitment to phase out LCPFAC chemical substances by the end of 2015 (Ref. 2). The objectives and rationale

for this proposed SNUR are explained in more detail in Unit III.

Table 1.--LCPFAC Chemical Substances Subject to Reporting After December 31, 2015

CAS Registry	Accession CAS Number	Chemical Name		
Number (CASRN)	CAS Number			
507-63-1	No Accession Number	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-		
678-39-7	No Accession Number	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-		
865-86-1	No Accession Number	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12- heneicosafluoro-		
2043-53-0	No Accession Number	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8- heptadecafluoro-10-iodo-		
2043-54-1	No Accession Number	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10 ,10-heneicosafluoro-12-iodo-		
17741-60-5	No Accession Number	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11, 12,12,12-heneicosafluorododecyl ester		
27905-45-9	No Accession Number	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester		
30046-31-2	No Accession Number	Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12- pentacosafluoro-14-iodo-		
39239-77-5	No Accession Number	1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14, 14-pentacosafluoro-		
60699-51-6	No Accession Number	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14, 15,15,16,16,16-nonacosafluoro-		
65510-55-6	No Accession Number	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13, 13,14,14-nonacosafluoro-16-iodo-		
68187-47-3	No Accession Number	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3-[(.gammaomegaperfluoro- C4-16-alkyl)thio]propyl]amino] derivs., sodium salts		
68391-08-2	No Accession Number	Alcohols, C8-14, .gammaomegaperfluoro		
70969-47-0	No Accession Number	Thiols, C8-20, .gammaomegaperfluoro, telomers with acrylamide		
125476-71-3	No Accession Number	Silicic acid (H ₄ SiO ₄), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol		

1078712-88-5	No Accession Number	Thiols, C4-20, .gammaomegaperfluoro, telomers with acrylamide and acrylic acid, sodium salts	
1078715-61-3	No Accession Number	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-[2-[(.gammaomegaperfluoro-C4-20-a lkyl)thio]acetyl] derivs., inner salts	
CBI	71217	Polyfluoroalkyl betaine	
CBI	89419	Modified fluoroalkyl urethane	
CBI	274147	Perfluorinated polyamine	

CBI = Confidential Business Information. CAS or CASRN = Chemical Abstracts Service Registry Number.

In this proposed rule, the term LCPFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. The category of LCPFAC chemical substances also includes the salts and precursors of these perfluorinated carboxylates. See Unit II.A. for the specific definition of the LCPFAC category.

PFOA and its salts are subject to this proposed rule. PFOA and examples of PFOA salts with Chemical Abstract Service Registry Numbers (CASRN) and chemical names are shown in Table 2 of this unit. PFOA and its salts are considered LCPFAC chemical substances. EPA believes all uses of PFOA and its salts were phased out by December 31, 2013.

Table 2.--PFOA and Examples of Its Salts

CAS Registry	Chemical Name		
Number			
(CASRN)			
335-66-0	Octanoyl fluoride, pentadecafluoro-		
335-67-1	Octanoic acid, pentadecafluoro- (PFOA)		
335-93-3	Octanoic acid, pentadecafluoro-, silver salt		
335-95-5	Octanoic acid, pentadecafluoro-, sodium salt		
2395-00-8	Octanoic acid, pentadecafluoro-, potassium salt		
3825-26-1	Octanoic acid, pentadecafluoro-, ammonium salt (APFO)		

CAS or **CASRN** = Chemical Abstracts Service Registry Number.

The PFAS chemical substances for which EPA is modifying an existing SNUR

are currently listed in 40 CFR 721.9582(a)(1). All of these chemical substances are collectively referred to in this rule as perfluoroalkyl sulfonates, or PFAS chemical substances. In this proposal, the term PFAS refers to a category of perfluorinated sulfonate chemical substances of any chain length.

EPA will not designate ongoing uses as significant new uses when the final rule is promulgated, except for uses that will be phased out by the end of 2015. Persons who manufacture (including importers) or process any of the chemical substances included in the proposed SNUR for an ongoing use at the time this proposed rule is published would be free to continue without submitting a SNUN. Note, however, that uses not already ongoing as of the publication date of this proposed rule, and ongoing uses that will be phased out by the end of 2015, would not be considered ongoing uses if they later arise, even if they are in existence upon the issuance of a final rule. Furthermore, uses that are ongoing as of the publication date of this proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule (see Units IV. and VI. for further discussion of what constitutes an ongoing use). Persons who intend to begin or resume commercial manufacture or processing of the chemical substance(s) for a significant new use would have to comply with all applicable SNUN requirements.

The LCPFAC chemical substances identified in Table 1 of this unit are known to have current or recent ongoing uses on the basis of their inclusion in reports submitted to the Agency under the 2012 Chemical Data Reporting (CDR) rule. EPA particularly requests comment on whether any of the current uses of any of the specific chemical substances identified in Table 1 of this unit will continue to be ongoing after December 31, 2015. EPA also requests comment on whether there are currently any ongoing uses, including use as part of articles, of any of the remaining LCPFAC chemical substances

that were not identified during the 2012 CDR. Furthermore, EPA requests comment on whether there are any ongoing uses of PFOA or its salts, and whether PFAS chemical substances are currently imported as part of carpets. EPA would welcome specific documentation of any such ongoing use.

D. Why is the Agency Taking this Action?

These SNURs are necessary to ensure that EPA receives timely advance notice of any future manufacturing (including importing) and processing of these LCPFAC chemical substances for new uses that may produce changes in human and environmental exposures.

The rationale and objectives for this SNUR are explained in Unit III.

E. What are the Estimated Incremental Impacts of this Action?

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers (including importers) and processors of the chemical substances included in this proposed rule. The economic analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here.

In the event that a SNUN is submitted, costs are estimated to be less than \$8,589 per SNUN submission for large business submitters and \$6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. In addition, for persons exporting a chemical substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country, which is estimated to cost less than \$100 on average per notification. The proposed rule may also affect firms that plan to import articles that contain LCFPAC chemical substances, because, while not required by the SNUR, these parties may take additional steps to determine whether LCPFAC chemical substances are part of the articles that they are considering to import. In the accompanying Economic Analysis for this proposed SNUR, example steps (and their respective costs) that an importer might take to identify LCPFAC

chemicals in articles are provided. These can include gathering information through agreements with suppliers, declarations through databases or surveys, or use of a third party certification system. Additionally, importers may require suppliers to provide certificates of testing analysis of the products or perform their own laboratory testing of certain articles. EPA is unable to predict, however, what, if any, particular steps an importer might take; potential total costs were not estimated.

II. Chemical Substances Subject to this Proposed Rule

A. What LCPFAC Chemical Substances are Subject to this Proposed SNUR?

LCPFAC chemical substances are synthetic chemicals that do not occur naturally in the environment. The LCPFAC chemical substances identified in this unit, where 5 < n < 21 or 6 < m < 21:

- 1. $CF_3(CF_2)_n$ -COO'M where $M = H^+$ or any other group where a formal dissociation can be made.;
 - 2. $CF_3(CF_2)_n$ -CH=CH₂.
 - 3. $CF_3(CF_2)_n$ -C(=O)-X where X is any chemical moiety.
 - 4. $CF_3(CF_2)_m$ - CH_2 -X where X is any chemical moiety.
- 5. $CF_3(CF_2)_m$ -Y-X where Y = non-S, non-N heteroatom and where X is any chemical moiety.

This category definition of LCPFAC chemical substances, based on the chemical structures in this unit, refers to a group of chemical substances containing PFOA and its higher homologues. The category also includes the salts and precursors of these chemical substances. The precursors may be simple derivatives of PFOA and higher homologues or polymers that contain or may degrade to PFOA or higher homologues. These precursors include long-chain fluorotelomers. LCPFAC chemical substances with greater

than 20 perfluorinated carbons can be considered polymers within the polymer exemption under 40 CFR 723.250 because they exceed a molecular weight of 1,000 daltons and contain at least 3 monomer units. As it is not EPA's intent to regulate fluoropolymers in this proposed rule, the LCPFAC category in this proposed rule includes a perfluorinated carbon chain length upper limit of 20.

In this proposed rule, PFOA and its salts includes the chemical substances listed in Table 2 of Unit II. PFOA and its salts are considered LCPFAC chemical substances.

Under this proposed rule, any LCPFAC chemical substance identified by 40 CFR 721.10536(b)(1)(i) through (b)(1)(v) that is intentionally used during fluoropolymer formulation, such as an emulsion stabilizer in aqueous dispersions, would be subject to reporting for the significant new uses described in 40 CFR 721.10536(b)(4)(i) through (b)(4)(iv). For example, ammonium perfluorooctanoate (APFO) -- when used as an aqueous dispersion agent in fluoropolymer production -- is subject to this SNUR if the final fluoropolymer product is used for a significant new use described in 40 CFR 721.10536(b)(4)(i) through (b)(4)(iv).

B. What PFAS Chemical Substances are Subject to this Proposed SNUR?

PFAS refers to a category of perfluorinated sulfonate chemical substances of any chain length. The PFAS chemical substances for which EPA is proposing to modify an existing SNUR are currently listed in 40 CFR 721.9582(a)(1).

C. What are the Uses and Production Levels of LCPFAC Chemical Substances?

PFOA, a member of the LCPFAC category, is a synthetic (man-made) chemical that does not occur naturally in the environment. PFOA is manufactured for use primarily as an aqueous dispersion agent as the ammonium salt in the manufacture of fluoropolymers. PFOA can also be produced unintentionally by the degradation of some

fluorotelomers, which are not manufactured using PFOA but could degrade to PFOA. DuPont, which was the last company to manufacture (including import) PFOA and its salts in the United States, ceased all production (including import) of PFOA and its salts in 2013 (Ref. 3).

Fluoropolymers provide nonstick surfaces for cookware and other products, are used as molded automotive parts, and have many other applications.

Polytetrafluoroethylene (PTFE) is the dominant fluoropolymer, accounting for 58% (by weight) of world fluoropolymer consumption in 2012 (Ref. 4). The United States accounted for 20% of the world consumption of PTFE in 2012 and 40% of the world consumption of other fluoropolymers.

Fluorotelomers, oligomers of tetrafluoroethylene, are relatively small functionalized molecules used to make polymers and surfactants. World-wide production of fluorotelomer-based polymers (FTBP) was estimated at 20 million pounds in 2006. Fluorotelomer monomers and FTBP are included in the LCPFAC category definition as potential LCPFAC precursors (Ref. 5). The United States accounts for more than 50% of world-wide fluorotelomer/FTPB production. Textiles and apparel account for approximately 50% of the volume used (Ref. 1).

In January 2006, EPA launched the 2010/2015 PFOA Stewardship Program (PFOA Stewardship Program) in partnership with eight companies: DuPont, Solvay Solexis, Asahi Glass Company, Daikin America, Inc., Clariant International Ltd., 3M/Dyneon, Arkema Inc., and BASF (formerly Ciba Specialty Chemicals Corporation) (Ref. 2). These companies represent a majority of global manufacture of LCPFAC chemical substances (Ref. 6). The program set a goal of reducing facility emissions and product content of LCPFAC chemical substances on a global basis by 95%, no later than

2010, and to eliminate emissions and product content of these chemical substances by 2015. With the exception of one manufacturer who has not participated in the PFOA Stewardship Program, these companies accounted for the total volume of LCPFAC chemical substances reported on the 2012 CDR (see Table 2 of Unit I.). Since these chemical substances are proprietary chemicals, they are not expected to be manufactured by any other company. The eight participating companies have informed EPA that they are on track to phase out LCPFAC chemical substances by the end of 2015 (Ref. 7).

Based on the 2012 CDR, there was one additional manufacturer of certain LCPFAC chemical substances who has not participated in the PFOA Stewardship Program. This company manufactures a small volume of LCPFAC chemical substances, compared to the volume of LCPFAC chemical substances manufactured by PFOA Stewardship Program companies, and those chemicals are primarily used in firefighting foams. This company has expressed an interest in participating in the phase out goal of the PFOA Stewardship Program and has already submitted premanufacture notices (PMNs) for chemical substitutes of their current LCPFAC chemical substances. Other than the PFOA Stewardship Program companies and this one company, there were no other companies that reported manufacture (including import) of LCPFAC chemical substances in the 2012 CDR. Any domestic companies still manufacturing LCPFAC chemical substances are most likely obtaining the feedstocks for that manufacturing process from companies participating in the PFOA Stewardship Program. For these companies to continue manufacturing LCPFAC chemical substances, they would need the feedstock and finished LCPFAC chemical substances currently supplied by companies participating in the PFOA Stewardship Program. As the PFOA Stewardship Program member companies phase out their manufacture of those substances and

customer demand continues to shift from LCPFAC chemical substances to alternatives, EPA believes that the manufacture of LCPFAC chemical substances by companies not participating in the PFOA Stewardship Programs are likely to cease by December 31, 2015. EPA would like to receive comments addressing the extent to which companies manufacturing specific LCPFAC chemical substances for particular uses are utilizing existing sources that are not dependent on the PFOA Stewardship Program member companies and that are expected to continue after December 31, 2015. Because specific uses of those specific chemical substances would be considered ongoing, they would be outside the scope of the significant new use when finalized.

D. What are the Uses and Production Levels of PFAS Chemical Substances?

The Agency previously determined that the 271 PFAS chemical substances identified in 40 CFR 721.9582(a)(1) were no longer being manufactured for any use in the United States, other than for the uses listed under 40 CFR 721.9582(a)(3), (a)(4), and (a)(5) (Refs. 8 and 9). PFAS chemical substances included in 40 CFR 721.9582 were previously used in a variety of products, which can be divided into three main use categories: Surface treatments, paper protection, and performance chemicals. In the past, PFAS chemical substances in the performance chemicals category were used in a wide variety of specialized industrial, commercial, and consumer applications. Specific applications included firefighting foams, mining and oil well surfactants, acid mist suppressants for metal plating and electronic etching baths, alkaline cleaners, floor polishes, inks, photographic film, denture cleaners, shampoos, chemical intermediates, coating additives, carpet spot cleaners, and as an insecticide in bait stations for ants (Ref. 10). In some instances, PFAS chemical substances are no longer used for the uses listed in 40 CFR 721.9582(a)(3), (a)(4), and (a)(5) as a result of new substitutes developed and

production and processing changes implemented by companies to eliminate the need for use of PFAS chemical substances. In addition, since those chemicals are no longer manufactured (including imported) other than for the listed uses, EPA believes that those chemical substances are also no longer processed other than for those listed uses.

E. What are the Potential Health and Environmental Effects of LCPFAC Chemical Substances?

The following brief summary of chemistry, environmental fate, exposure pathways, and health and environmental effects of LCPFAC chemical substances is based on the 2009 Action Plan (Ref. 1), references cited in the 2009 Action Plan, and additional selected references published after the 2009 Action Plan.

PFOA is persistent, widely present in humans and the environment, has long half-lives in humans, and can cause adverse effects in laboratory animals, including cancer and developmental and systemic toxicity (Refs. 11, 12, 13, 14, and 15). PFOA precursors, chemicals which degrade or may degrade to PFOA, are also present worldwide in humans and the environment and, in some cases, might be present at higher concentrations than PFOA and be more toxic (Refs. 16, 17, 18, 19, and 20). PFOA higher homologues are chemicals with carbon chain lengths longer than PFOA. Available evidence suggests that toxicity and bioaccumulation appear to be higher for chemical substances with longer carbon chain lengths compared to those with shorter chain lengths (Refs. 21, 22, 23, and 24).

LCPFAC chemical substances have been detected in biota, air, water, dust, and soil samples collected throughout the world. Some LCPFAC chemical substances have the potential for long-range transport. They are transported over long distances by a combination of dissolved-phase ocean and gas-phase atmospheric transport; however,

determining which is the predominant transport pathway is complicated by many factors, including the uncertainty over water to atmosphere partitioning. Furthermore, there is evidence that transport and subsequent oxidation of volatile alcohol LCPFAC chemical substance precursors contribute to the levels of LCPFAC chemical substances in the environment.

For a more detailed summary of background information (e.g., chemistry, environmental fate, exposure pathways, and health and environmental effects), as well as references pertaining to LCPFAC chemical substances, please refer to Unit IV. of EPA's initial proposed SNUR on LCPFAC chemical substances published in the **Federal Register** of August 15, 2012 (Ref. 10).

F. What are the Potential Health and Environmental Effects of PFAS Chemical Substances?

PFAS chemical substances degrade ultimately to perfluoroalkylsulfonic acid (PFASA), which can exist in the anionic form under environmental conditions. Further degradation of PFASA is not observed under normal environmental conditions. PFASA is highly persistent in the environment and has a tendency to bioaccumulate (Ref. 25). PFASA can continue to be formed by any PFAS containing chemical substances introduced into the environment.

Studies have found PFAS chemical substances containing 5 to 14 carbons (C5-C14) in the blood of the general human population as well as in wildlife, indicating that exposure to these chemical substances is widespread (Refs. 1, 4, 26, 27, 28, and 29). The widespread presence of PFAS chemical substances in human blood samples nationwide suggests other pathways of exposure, possibly including the release of PFAS from treated articles.

Biological sampling has shown the presence of certain perfluoroalkyl compounds in fish and in fish-eating birds across the United States and in locations in Canada, Sweden, and the South Pacific (Refs. 26 and 27). The wide distribution of the chemical substances in high trophic levels is strongly suggestive of the potential for bioaccumulation and/or bioconcentration.

Based on currently available information, EPA believes that while all PFAS chemical substances are expected to persist, the length of the perfluorinated chain may also have an effect on bioaccumulation and toxicity, which are also characteristics of concern for these chemical substances. PFAS chemical substances with longer carbon chain lengths may be of greater concern than those with shorter chain lengths (Refs. 4, 21, and 22).

The hazard assessment published by the Organization for Economic Cooperation and Development (Ref. 10) concluded that perfluorooctyl sulfonates (PFOS) are persistent, bioaccumulative and toxic to mammalian species. While most studies to date have focused primarily on PFOS, structure-activity relationship analysis indicates that the results of those studies are applicable to the entire category of PFAS chemical substances, which includes PFOS. Available test data have raised concerns about their potential developmental, reproductive, and systemic toxicity (Refs. 1, 16, 26, and 27).

For a more detailed summary of background information (e.g., chemistry, environmental fate, exposure pathways, and health and environmental effects), as well as references pertaining to PFAS chemical substances, please refer to EPA's proposed SNURs on PFAS chemical substances published in the **Federal Register** of October 18, 2000 (Ref. 30), March 11, 2002, and March 10, 2006 (Refs. 26 and 31). Also, refer to the 2009 Action Plan (Ref. 1).

III. Rationale and Objectives

A. Rationale

EPA is concerned about the effects LCPFAC and PFAS chemical substances may have on human health and the environment. As discussed in Unit II., LCPFAC and PFAS chemical substances are found world-wide in the environment, wildlife, and humans. They are bioaccumulative in wildlife and humans, and are persistent in the environment. They are toxic to laboratory animals, producing reproductive, developmental, and systemic effects in laboratory tests. The exact sources and pathways by which these chemicals move into and through the environment and allow humans and wildlife to become exposed are not fully understood, but are likely to include releases from manufacturing of the chemicals, processing of these chemicals into products, and aging, wear, and disposal of products containing them.

Since the manufacture and processing of LCPFAC chemical substances listed in Table 1 of Unit I. will be discontinued after December 31, 2015, as committed by the principal manufacturers of LCPFAC chemical substances participating in the PFOA Stewardship Program, EPA expects the presence of LCPFAC chemical substances in humans and the environment to decline over time as has been observed in the past when production and use of other persistent chemicals has ceased (Ref. 32). Similarly, EPA expects other LCPFAC chemicals substances to decline as well since the manufacture and processing of those has ceased, as observed by the absence of reporting in the CDR 2012 reporting period. In addition, EPA expects the presence of PFAS chemical substances to decline in humans and the environment since PFAS is no longer imported as part of carpets. EPA is concerned that the manufacturing or processing of these chemical substances for the proposed significant new uses could be reinitiated in the

future. If reinitiated, EPA believes that such use would significantly increase the magnitude and duration of exposure to humans and the environment to these chemical substances.

Accordingly, EPA wants the opportunity to evaluate and control, where appropriate, activities associated with those uses, if such manufacturing (including importing) or processing were to start or resume. The required notification provided by a SNUN would provide EPA with the opportunity to evaluate activities associated with a significant new use and an opportunity to protect against unreasonable risks, if any, from exposure to LCPFAC chemical substances.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

B. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use(s) that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process

LCPFAC chemical substances, PFOA or its salts, or PFAS chemical substances for the described significant new use before that activity begins.

- 2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing these chemical substances for the described significant new use.
- 3. EPA would be able to regulate prospective manufacturers or processors of these chemical substances before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of the LCPFAC and

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PFAS chemical substances subject to this proposed rule, as discussed in this unit. EPA considered relevant information about the toxicity of these substances, trends in blood levels, likely human exposures and environmental releases associated with possible uses, and the four factors listed in TSCA section 5(a)(2).

As discussed in Unit III.A., once the manufacture (including import) and processing of LCPFAC chemical substances for these uses discontinue in the United States, exposure will decrease over time. EPA expects their presence in humans and the environment to concomitantly decline over time. If any of the new use of LCPFAC chemical substances were to begin after phasing out, EPA believes that such use could both change the type and form and increase the magnitude and duration of human and environmental exposure to the substances, constituting a significant new use. Based on consideration of the statutory factors discussed herein, EPA has preliminary determined the following uses as significant new uses:

- Manufacturing (including importing) or processing of LCPFAC chemical substances listed in Table 1 of Unit I. for any uses that are no longer ongoing after December 31, 2015.
- Manufacturing (including importing) or processing of PFOA or its salts for any use.
- Manufacturing (including importing) or processing of all other LCPFAC chemical substances for any use not ongoing as of the date on which this proposed rule is published.

EPA's Office of Research and Development has conducted research demonstrating that perfluorinated chemicals contained in articles of commerce can be released from those articles. For instance, one study observed the removal of

perfluorinated chemicals from treated carpet as a result of carpet cleaning and showed that perfluorinated chemicals contained in treated carpet could be released to the environment (Ref. 33). A second study indicated that perfluorinated chemicals could be released from treated medical garments with water alone (Ref. 34). LCPFAC chemical substances may be similarly released from related articles. EPA believes that once manufacturing of LCPFAC chemical substances have been phased out, there will be fewer articles containing the chemicals substances in the public domain over time and thus, exposure through articles will decrease over time. EPA believes any new use of LCPFAC chemical substances as part of articles would increase the duration and magnitude of human and environmental exposure to the substances. Based on these considerations, EPA has preliminarily determined that importing LCPFAC chemical substances listed in Table 1 of Unit I. and PFOA or its salts as part of articles both constitutes a significant new use and warrants making the exemption at 40 CFR 721.45(f) inapplicable to importers of articles. However, import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of articles, containing PFOA or its salts was not determined to be a significant new use because this use is currently ongoing and EPA is not making inapplicable any of the standard exemptions at 40 CFR 721.45 for PFOA.

In a previous rule EPA designated all uses of the PFAS chemicals identified in 40 CFR 721.9582 as significant new uses, except the ongoing uses specified in 40 CFR 721.9582 (a)(3) through (a)(5), the Agency believes the manufacture (including import) and processing of any of the PFAS chemical substances subject to this rule has been discontinued, including the importing of these chemical substances as part of carpets.

Based on EPA's Office of Research and Development's research and the considerations

in the preceding paragraphs (see, e.g., Ref. 30), EPA believes that if the import of carpets containing these chemical substances were to resume, people and the environment could be exposed to these chemical substances in articles. The existing regulation at 40 CFR 721.9582 broadly defined the significant use in a way that encompassed import of these chemical substances as part of carpets, but for clarity EPA is proposing to expressly list import as part of carpets as a significant new use for the chemicals covered by 40 CFR 721.9582, and in light of the referenced considerations, EPA is now proposing to make inapplicable the exemption at 40 CFR 721.45 to importers of these chemical substances as part of articles.

As noted in Unit V., EPA is proposing that the exemption at 40 CFR 721.45(f) remain in effect for persons who process chemical substances as part of articles because existing stocks of articles may still contain LCPFAC or PFAS chemical substances.

Table 3 of this unit is a summary of the dates relevant to EPA's preliminary determinations.

Table 3.--Significant New Uses for LCPFAC Chemical Substances, PFOA and Its Salts, Other LCPFAC Chemical Substances, and PFAS Chemical Substances

New Use	LCPFAC in Table 1 of Unit I.	PFOA and its salts	Other LCPFAC	PFAS
Manufacture or processing for any use	After 12/31/2015	[insert date of publication in the Federal Register]	[insert date of publication in the Federal Register]	In effect (see 40 CFR 721.9582)

LCPFAC = Long-chain perfluoroalkyl carboxylate. PFAS = Perfluoroalkyl sulfonate. PFOA = Perfluorooctanoic acid.

V. Importers and Processors of These Chemical Substances as Part of Articles

Once the determination of a significant new use under TSCA section 5(a)(2) has been made, EPA may separately determine whether it would be appropriate to make the regulatory exemption for some or all persons who import or process a chemical substance

as part of an article (40 CFR 721.45(f)) inapplicable to a SNUR. In this case, EPA believes that the assumption underpinning this exemption, that people and the environment will generally not be exposed to chemical substances as part of articles, does not hold true. See Unit IV. for a discussion of why EPA believes this assumption is incorrect. Thus EPA is proposing to make this exemption inapplicable to importers of the PFAS chemicals identified in 40 CFR 721.9582 as part of carpets and importers of the chemical substances listed in Table 1 and Table 2 of Unit I.C. as part of an article for the corresponding significant new uses. EPA is requesting comment on the potential for exposure to these chemical substances via these articles and for comments on the ongoing uses of these chemical substances as part of an article. EPA is not proposing to make this exemption inapplicable to processors of these chemical substances as part of an article. EPA previously determined in a prior rulemaking and is not reopening its determination to make this exemption inapplicable to importers of the LCPFAC chemical substances identified in 40 CFR 721.10536(b)(1) as part of carpets.

VI. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. However, EPA is proposing that the exemption at 40 CFR 721.45(f) not apply to persons who import LCPFAC chemicals substances listed in Table 1 of Unit I., PFOA or its salts (See Table 2 of Unit I. for examples of PFOA salts), and PFAS chemicals substances listed in 40 CFR 721.9582. As a result, persons subject to the provisions of this proposed rule would not be exempt from significant new use reporting

if they import those LCPFAC chemical substances or PFOA or its salts as part of articles or if they import PFAS chemical substances as part of carpets. However, EPA is also proposing that the exemption at 40 CFR 721.45(f) remain in effect for persons who process chemical substances as part of an article because existing stocks of articles may still contain LCPFAC or PFAS chemical substances. Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in the proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. In accordance with 40 CFR 707.60(b), this proposed SNUR does not trigger notice of export for articles. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Such persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The TSCA section 13 import certification requirement applies to articles containing a chemical substance or mixture if

so required by the Administrator by a specific rule under TSCA. At this time EPA is not proposing to require import certification for these chemical substances as part of articles. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. VII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the Federal Register of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the document became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of the chemical substance(s) that would be regulated through this proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule (as EPA expects for the LCPFAC chemical substances listed in Table 1 of Unit I. and PFOA or its salts). To the extent that additional ongoing uses are found in the course of rulemaking, EPA would exclude those specific chemical substances for those specific uses from the final SNUR. EPA has

promulgated provisions to allow persons to comply with the final SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

- Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
- Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25; and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with the Agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- 1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance.
 - 2. Potential benefits of the chemical substance.
- 3. Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. e-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

X. Economic Analysis

A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this proposed rule (Ref. 35). In the event that a SNUN is submitted, costs are

estimated at approximately \$8,589 per SNUN submission for large business submitters and \$6,189 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). The costs of submission of SNUNs will not be incurred by any company unless a company decides to pursue a significant new use as defined in this proposed SNUR.

The proposed SNUR would require notification to EPA before the importation of articles containing LCPFAC chemical substances listed in Table 1 of Unit I., or PFOA and its salts. While not required by the proposed SNUR, companies importing articles containing these chemical substances may take additional steps to determine whether these chemical substances are part of the articles they are considering to import.

Companies typically have an understanding of the contents of the articles they import or process; however, there may be instances when companies decide to gather additional information about these articles from suppliers if not currently available. EPA believes that the costs associated with such information gathering activities would be minimal for this proposed SNUR because these chemical substances are unlikely to be available for use in articles after December 31, 2015. EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 35).

B. Export Notification

Under TSCA section 12(b) and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or

promulgated under TSCA section 5. For persons exporting a chemical substance that is the subject of a SNUR, a one-time notice must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (i.e., the number of countries to which the chemical substance is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical substance covered in this proposed rule SNUR, as stated in the accompanying EA of this proposed SNUR, the estimated cost of the export notification requirement on a per unit basis is \$81.04.

C. Import Chemical Substances as Part of an Article

In proposing to make inapplicable the exemption relating to persons that import certain chemical substances as part of an article, this action may affect firms that plan to import types of articles that may contain the subject chemical substance. Some firms have an understanding of the contents of the articles they import. However, EPA acknowledges that importers of articles may have varying levels of knowledge about the chemical content of the articles that they import. These parties may need to become familiar with the requirements of the proposed rule. And, while not required by the SNUR, these parties may take additional steps to determine whether the subject chemical substances are part of the articles that they are considering to import. This determination may involve activities such as gathering information from suppliers along the supply chain, and/or testing samples of the article itself. Costs vary across the activities chosen and the extent of familiarity a firm has regarding the articles it imports. Cost ranges are presented in the Agency's Economic Analysis for this proposed rule (Ref. 35). Based on available information, EPA believes that article importers that

choose to investigate their products would incur costs at the lower end of the ranges presented in the Economic Analysis. For those companies choosing to undertake actions to assess the composition of the articles they import, EPA expects that importers would take actions that are commensurate with the company's perceived likelihood that a chemical substance might be a part of an article, and the resources it has available. Example activities and their costs are provided in the accompanying Economic Analysis of this proposed rule (Ref. 32).

XI. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory actions:

A. Promulgate a TSCA Section 8(a) Reporting Rule

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the Agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for LCPFAC and PFAS chemical substances, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements. In view of the level of health and environmental concerns about LCPFAC and PFAS chemical substances if used for the proposed significant new use, EPA believes that a TSCA section 8(a) rule for this

chemical substance would not meet EPA's regulatory objectives.

B. Regulate LCPFAC Chemical Substances Under TSCA Section 6

EPA may regulate under TSCA section 6 if "the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment." (TSCA section 6(a)). Given that these chemical substances are believed to be phasing out, EPA concluded that risk management action under TSCA section 6 is not necessary at this time. However, if EPA determines that there are persons who intend to manufacture or process these chemicals, EPA may decide to regulate LCPFAC chemical substances under TSCA section 6. This proposed SNUR would allow the Agency to address the potential risks associated with the proposed significant new use.

XII. Request for Comment

A. Do You Have Comments or Information About Ongoing Uses?

EPA welcomes comments on any aspect of this proposed SNUR. EPA particularly requests comment on whether any of the current uses of any of the specific LCPFAC chemical substances identified in Table 1 of Unit I. will continue to be ongoing after December 31, 2015, or whether there are any ongoing uses of those identified in Table 2 of Unit I. EPA also requests comment on whether there are currently any ongoing uses, including use as part of articles, of any of the remaining LCPFAC chemical substances that were not identified in the 2012 CDR. EPA would welcome specific documentation of any such ongoing use.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. It is EPA's policy to include all comments received in the

public docket without change or further notice to the commenter and to make the comments available online at http://www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

- 2. Tips for preparing your comments. When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

- 1. EPA. Long-Chain Perfluorinated Chemicals Action Plan. December 30, 2009.
- 2. EPA. 2010/2015 PFOA Stewardship Program. 2006.

http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html.

- 3. Rizzuto, Pat. DuPont Ceases PFOA Manufacture, Is on Track to Stop All Uses By End of 2014. *Bloomberg BNA Daily Environmental Report*. December 5, 2013.
 - 4. 3M Company. Perfluorooctane Sulfonate: Current Summary of Human Sera, Health and Toxicology Data. St. Paul, Minnesota. January 21, 1999.
- 5. Washington, J.W., et al. Degradability of an Acrylate-Linked Fluorotelomer Polymer in Soil. *Environmental Science and Technology*. 43: 6617-6623. 2009.
- 6. EPA. PFOA Stewardship Program Baseline Year Summary Report. 2007. http://epa.gov/oppt/pfoa/pubs/stewardship/sumrpt.html#background.
 - 7. EPA. Industry Progressing in Voluntary Effort to Reduce Toxic Chemicals.

- February 10, 2012.
- 8. EPA. Perfluoroalkyl Sulfonates; Significant New Use Rule. Final Rule. **Federal Register** (67 FR 72854, December 9, 2002) (FRL-7279-1).
- 9. EPA. Perfluoroalkyl Sulfonates; Significant New Use Rule. Final Rule. **Federal Register** (72 FR 57222, October 9, 2007) (FRL-8150-4).
- 10. EPA. Perfluoroalkyl Sulfonates and Long-Chain Perfluoroalkyl Carboxylate Chemical Substances; Proposed Significant New Use Rule; Proposed Rule. **Federal Register** (77 FR 48924, August 15, 2012) (FRL-9358-7).
- 11. Butt, C.M., et al. Levels and Trends of Poly- and Perfluorinated Compounds in the Arctic Environment. *Science Total Environment*. 408: 2936-2965. 2010.
- 12. Houde M., et al. Biological Monitoring of Polyfluoroalkyl Substances: A Review. *Environmental Science and Technology*. 40: 3463-3473. 2006.
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- 14. Lau C., et al. Effects of Perfluoroctanoic Acid Exposure During Pregnancy in the Mouse. *Toxicology Science*. 90(2): 510-518. 2006.
- 15. Lau C., et al. Perfluoroalkyl Acids: A Review of Monitoring and Toxicological Findings. *Toxicological Sciences*. 99(2): 366-394. 2007.
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- Humans. Environmental Chemistry. 7: 457-484. 2010.
- 18. Lau, C. Perfluorinated Compounds. *Molecular, Clinical and Environmental Toxicology Experientia Supplementum*. Volume 101, pp. 47-86. 2012.
- 19. Yoo, H., et al. Concentrations, Distribution and Persistence of Fluorotelomer Alcohols in Sludge-applied Soils Near Decatur, Alabama, USA. *Environmental Science & Technology*. 44: 8397-8402. 2010.
- 20. Washington, J.W., et al. Concentrations, Distribution and Persistence of Perfluoroalkylates in Sludge-applied Soils Near Decatur, Alabama, USA. *Environmental Science and Technology.* 44: 8390-8396. 2010.
- 21. Kudo, N., et.al. Comparison of the Elimination Between Perfluorinated Fatty Acids with Different Carbon Chain Lengths in Rats. *Chemico-Biological Interactions*. Volume 134(2), pp. 203-216. 2001.
- 22. Goecke-Flora, C.M., et al. Influence of Carbon Chain Length on the Hepatic Effects of Perfluorinated Fatty Acids, A\19\ F- and \31\P-NMR Investigation. *Chemical Research in Toxicology.* 9(4), pp. 689-695. 1996.
- 23. Lasier, P.J., et al. Perfluorinated Chemicals in Surface Waters and Sediments from Northwest Georgia, USA, and Their Bioaccumulation in Lumbriculus Variegates. *Environmental Toxicology and Chemistry*. 30: 2194-2201. 2011.
- 24. 3M Company. Fluorochemical Use, Distribution, and Release Overview. St. Paul, Minnesota. May 26, 1999.
- 25. Lua, C. Perfluorinated Compounds. *Molecular, Clinical and Environmental Toxicology Experientia Supplementum*. Volume 101, pp. 47-86. 2012.
- 26. EPA. Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule; Proposed Rule. **Federal Register** (67 FR 11014, March 11, 2002) (FRL-6823-7).

- 27. EPA. Perfluoroalkyl Sulfonates; Significant New Use Rule; Final Rule. **Federal Register** (67 FR 11008, March 11, 2002) (FRL-6823-6).
- 28. 3M Company. The Science of Organic Fluorochemistry. St. Paul, Minnesota. February 5, 1999.
- 29. Centers for Disease Control and Prevention. Fourth National Report on Human Exposure to Environmental Chemicals. Updated Tables. March 2013.
- 30. EPA. Perfluoroalkyl Sulfonates; Significant New Use Rule; Proposed Rule. **Federal Register** (65 FR 62319, October 18, 2000) (FRL-6745-5).
- 31. EPA. Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule; Proposed Rule. **Federal Register** (71 FR 12311, March 10, 2006) (FRL-7740-6).
- 32. Kato, K. et al. Trends in Exposure to Polyfluoroalkyl Chemicals in the U.S. Population: 1999-2008. *Environmental Science and Technology*. 45: 8037-8045. 2011.
- 33. Hubbard, H. et al. Removal of Perfluorocarboxylic Acids (PFCAs) from Carpets Treated with Stain-Protection Products by Using Carpet Cleaning Machines. EPA, Report EPA/600-12/703. 2012.
- 34. Liu, X. et al. Trends of Perfluoroalkyl Acid Content in Articles of Commerce. EPA, Report EPA/600/R-12/585. 2012.
- 35. EPA. Economic Analysis of the Significant New use Rule for Long-Chain Perfluoroalkyl Carboxylate Chemical Substances. August 20, 2013.
- 36. EPA. Modification of Significant New Use Rules for Certain Substances; Final Rule. **Federal Register** (62 FR 42690, August 8, 1997) (FRL-5735-4).

XIV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed SNUR has been designated by the Office of Management and Budget (OMB) as a "significant regulatory action" under section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, EPA submitted this proposed action to OMB for review under Executive Order 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket.

B. Paperwork Reduction Act (PRA)

This action would not impose any new information collection burden under PRA, 44 U.S.C. 3501 *et seq*. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for an export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system. Additional burden, estimated to be less than 10 hours, could be incurred where additional recordkeeping requirements are specified under 40 CFR 721.125(a), (b), and (c).

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the

Federal Register, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this proposed SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

EPA generally finds that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities (See, e.g., Ref. 36). Since these proposed SNURs would require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact would occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to engage in such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005-2011, only three submitters self-identified as small in their SNUN submission (Ref. 35). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm and that the requirement to submit a SNUN generally does not have a significant economic impact.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." EPA has preliminarily determined, based in part, on the Agency's market research, that these chemical substances are not being manufactured (including imported) or processed for a significant new use. This preliminary determination also includes importation of these chemical substances as part of articles for the significant new use (Unit IV.).

In addition, given existing regulatory limitations both internationally and within the U.S., industry-wide processes, resources that support companies in understanding and managing their supply chains, and the evidence showing minimal worldwide availability of the LCPFACs regulated under the SNUR, EPA believes that there will be minimal impact to importers of these chemical substances as part of articles from this proposed SNUR. Therefore, based on current knowledge, EPA has preliminarily determined that these uses, including the importation of these chemical substances as part of articles, are not ongoing, and that no small entities presently manufacture for the significant new uses addressed in this proposed rule. EPA will consider information received during the comment period that might indicate that this preliminary determination is incorrect. The SNUR does not require importers of articles to conduct specific activities to ascertain if they are importing an article that uses a chemical subject to the proposed rule. EPA expects importers would take actions that are commensurate with their perceived likelihood of a chemical substance subject to the SNUR being part of an article, and the resources it has available. EPA has no reason to believe that a firm would voluntarily incur substantial costs to comply with the SNUR, but rather each firm will choose the most efficient route to identify whether it is importing the subject chemical substances in articles.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this proposed rulemaking. As such, the requirements of UMRA sections 202, 203, 204, or 205, 2 U.S.C. 1531-1538, do not apply to this proposed action.

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have Tribal implications because it is not expected to have any effect (i.e., there would be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this proposed rule.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This proposed action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this proposed action is not intended to address environmental health or safety risks for children.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer Advancement Act (NTTAA)

Since this proposed action does not involve any technical standards, section 12(d) of the NTTAA, 15 U.S.C. 272 note, does not apply to this proposed action.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This proposed action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this proposed action would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This proposed action would not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 18, 2014.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

- 2. In § 721.9582:
 - a. Redesignate paragraph (a) as (b).
 - b. Add new paragraph (a).
 - c. Revise newly designated paragraph (b)(2)(iv).
 - d. Add paragraph (c).

The amendments read as follows:

§ 721.9582 Certain perfluoroalkyl sulfonates.

(a) *Definitions*. The definitions in § 721.3 apply to this section. In addition, the following definition applies:

Carpet means a finished fabric or similar product intended to be used as a floor covering. This definition excludes resilient floor coverings such as linoleum and vinyl tile.

- (b) * * *
- (2) * * *
- (iv) Import as part of carpets.
- * * * * *
- (c) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (c).
- (1) Revocation of certain notification exemptions. With respect to imports of carpets, the provisions of § 721.45(f) do not apply to this section. A person who imports a

chemical substance identified in this section as part of a carpet is not exempt from submitting a significant new use notice. The other provision of § 721.45(f), respecting processing a chemical substance as part of an article, remains applicable.

- (2) [Reserved]
- 3. Revise § 721.10536 to read as follows:

§ 721.10536 Long-chain perfluoroalkyl carboxylate chemical substances.

(a) *Definitions*. The definitions in § 721.3 apply to this section. In addition, the following definition applies:

Carpet means a finished fabric or similar product intended to be used as a floor covering. This definition excludes resilient floor coverings such as linoleum and vinyl tile.

- (b) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified below, where 5 < n < 21 or 6 < m < 21, are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(i) and (b)(4)(iv) of this section.
- (i) $CF_3(CF_2)_n$ -COO⁻M where $M = H^+$ or any other group where a formal dissociation can be made.
 - (ii) $CF_3(CF_2)_n$ -CH=CH₂.
 - (iii) $CF_3(CF_2)_n$ -C(=O)-X where X is any chemical moiety.
 - (iv) CF₃(CF₂)_m-CH₂-X where X is any chemical moiety.
- (v) $CF_3(CF_2)_m$ -Y-X where Y = non-S, non-N heteroatom and where X is any chemical moiety.

(2) The chemical substances listed in Table 1 of this paragraph are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(ii) of this section.

Table 1.--LCPFAC Chemical Substances Subject to Reporting After December 31, 2015

CAS Registry Number (CASRN)	Accession Number	Chemical Name
507-63-1	No Accession Number	Octane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-8-iodo-
678-39-7	No Accession Number	1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-
865-86-1	No Accession Number	1-Dodecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12- heneicosafluoro-
2043-53-0	No Accession Number	Decane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-heptadecafluoro-10-iodo-
2043-54-1	No Accession Number	Dodecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10 ,10-heneicosafluoro-12-iodo-
17741-60-5	No Accession Number	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11, 12,12,12-heneicosafluorododecyl ester
27905-45-9	No Accession Number	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl ester
30046-31-2	No Accession Number	Tetradecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12- pentacosafluoro-14-iodo-
39239-77-5	No Accession Number	1-Tetradecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14, 14-pentacosafluoro-
60699-51-6	No Accession Number	1-Hexadecanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14, 15,15,16,16,16-nonacosafluoro-
65510-55-6	No Accession Number	Hexadecane, 1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13, 13,14,14-nonacosafluoro-16-iodo-
68187-47-3	No Accession Number	1-Propanesulfonic acid, 2-methyl-, 2-[[1-oxo-3- [(.gammaomegaperfluoro- C4-16- alkyl)thio]propyl]amino] derivs., sodium salts
68391-08-2	No Accession Number	Alcohols, C8-14, .gammaomegaperfluoro
70969-47-0	No Accession Number	Thiols, C8-20, .gammaomegaperfluoro, telomers with acrylamide

125476-71-3	No Accession Number	Silicic acid (H ₄ SiO4), sodium salt (1:2), reaction products with chlorotrimethylsilane and 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro-1-decanol
1078712-88-5	No Accession Number	Thiols, C4-20, .gammaomegaperfluoro, telomers with acrylamide and acrylic acid, sodium salts
1078715-61-3	No Accession Number	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-[2-[(.gammaomegaperfluoro-C4-20-a lkyl)thio]acetyl] derivs., inner salts
CBI	71217	Polyfluoroalkyl betaine
CBI	89419	Modified fluoroalkyl urethane
CBI	274147	Perfluorinated polyamine

CBI = Confidential Business Information. CAS or CASRN = Chemical Abstracts Service Registry Number.

(3) The chemical substances identified as perfluorooctanoic acid (PFOA) and its salts, including those listed in Table 2 of this paragraph, are subject to reporting under this section for the significant new uses described in paragraph (b)(4)(iii) of this section.

Table 2.--PFOA and Examples of Its Salts

CAS Registry Number (CASRN)	Chemical Name
335-66-0	Octanoyl fluoride, pentadecafluoro-
335-67-1	Octanoic acid, pentadecafluoro- (PFOA)
335-93-3	Octanoic acid, pentadecafluoro-, silver salt
335-95-5	Octanoic acid, pentadecafluoro-, sodium salt
2395-00-8	Octanoic acid, pentadecafluoro-, potassium salt
3825-26-1	Octanoic acid, pentadecafluoro-, ammonium salt (APFO)

CAS or CASRN = Chemical Abstracts Service Registry Number.

- (4) Significant new uses. (i) The significant new use for chemical substances identified in paragraph (b)(1) of this section are: Manufacture (including import) or processing for use as part of carpets or to treat carpets (e.g., for use in the carpet aftercare market).
- (ii) The significant new use for chemical substances identified in paragraph (b)(2) of this section are: Manufacture (including import) or processing for any use after December 31, 2015.

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(iii) The significant new use for chemical substances identified in paragraph

(b)(3) of this section are: Manufacture (including import) or processing for any use.

Import of fluoropolymer dispersions and emulsions, and fluoropolymers as part of

articles, containing chemical substances identified in paragraph (b)(3) of this section shall

not be considered as a significant new use subject to reporting.

(iv) The significant new use for chemical substances identified in paragraph (b)(1)

of this section, except for those chemicals identified in Table 1 of paragraph (b)(2) of this

section are: Manufacture (including import) or processing for any use other than that use

already covered by paragraph (b)(4)(i) of this section.

(c) Specific requirements. The provisions of subpart A of this part apply to this

section except as modified by this paragraph (c).

(1) Revocation of certain notification exemptions. With respect to imports of

carpets, the provisions of § 721.45(f) do not apply to this section. With respect to imports

of articles, the provisions of § 721.45(f) also do not apply to a chemical substance

identified in paragraphs (b)(2) or (b)(3) of this section. A person who imports a chemical

substance identified in paragraph (b)(1) of this section as part of a carpet or who imports

a chemical substance identified in paragraphs (b)(2) or (b)(3) of this section as part of an

article is not exempt from submitting a significant new use notice. The other provision of

§ 721.45(f), respecting processing a chemical substance as part of an article, remains

applicable.

(2) [Reserved]